



NCI Central IRB Study Activity Update December 31, 2008

The CIRB is distributing this study activity update to notify its participating institutions of recent information and documentation for current CIRB protocols. Information about protocol-specific addenda or memoranda issued by the Cooperative Groups, activations/closures of CIRB protocols, drug notices and safety reports, general CIRB memoranda and notices will be included in these broadcast summaries.

The protocol-specific information in this email refers to amendment/revision documentation approved by CIRB and NCI CTEP. Information about new studies refers to protocols that have been approved by the CIRB and NCI CTEP and activated by the Lead Cooperative Group.

These documents are posted within each protocol's document list inside the Participant's Area of the CIRB website (www.ncicirb.org). This is a protected site - you will be required to enter your username and password in order to access the Participant's Area. If you are unsure of your login information or have difficulty accessing the site/documents, please email ncicirbcontact@emmes.com or call the CIRB at 888-657-3711.

General CIRB Documentation

If other individuals at your institution need to receive this email or other CIRB Correspondence please have them email ncicirbcontact@emmes.com with their request.

****Note:** All documentation can be accessed through the What's New section of the CIRB website (<http://www.ncicirb.org>). ******

Protocol Specific Documentation (listed by protocol)

****Note:** All documentation can be accessed through the Participant's Area (http://www.ncicirb.org/CIRB_Login.asp) of the CIRB website. ******



Other Activity Posted:

ACOSOG-Z1041 A1

Amendment Review (AR) Amendment #3 (Protocol Version Date 09/18/08)

Documents Posted:

- 11/07/08: Minutes – Amendment 3

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

CALGB-30610

Amendment Review (AR): Update #1 Approval 12/05/08 (Protocol Version Date 10/28/08)

Documents Posted:

- 12/15/08: Change Memo (Protocol Version Date 10/28/08)
- CIRB Application (Protocol Version Date 10/28/08)
- Summary of CIRB Application Revisions (Protocol Version Date 10/28/08)
- 12/12/08: CIRB Approval Letter Update 1 (Protocol Version Date 10/28/08)
- Protocol Version Date 10/28/08
- Informed Consent Document for Protocol Version Date 10/28/08 [Up1]
- 12/05/08: Primary Reviewer 1 Comments

CALGB-49907

Continuing Review (CR): Approval 11/12/08 (Protocol Version Date 01/31/07)

Documents Posted:

- 11/12/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

CALGB-80101

Amendment Review (AR): **Protocol Notice: Shortage of Leucovorin**

Documents Posted:

- 12/24/08: CIRB Approval of Shortage of Leucovorin PI Letter

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

CALGB-SWOG-C80405

Amendment Review (AR): Effective December 12, 2008, CALGB/SWOG 80405, has been Reactivated

Documents Posted:

- 12/17/08: CIRB Acknowledgement of Reactivation Memo
- 12/12/08: CALGB Reactivation Memo



CALGB-SWOG-C80405

Amendment Review (AR): **Protocol Notice: Shortage of Leucovorin**

Documents Posted:

- 12/24/08: CIRB Approval of Shortage of Leucovorin PI Letter

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

COG-AALL0331

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**

Documents Posted:

- 12/12/08: CIRB Acknowledgement of Leucovorin Shortage Memo
- 11/25/08: COG Temporary Shortage of Leucovorin Letter

COG-AALL0433

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**

Documents Posted:

- 12/12/08: CIRB Acknowledgement of Leucovorin Shortage Memo
- 11/25/08: COG Temporary Shortage of Leucovorin Letter

COG-AALL0434

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**

Documents Posted:

- 12/12/08: CIRB Acknowledgement of Leucovorin Shortage Memo
- 11/25/08: COG Temporary Shortage of Leucovorin Letter

COG-AALL0631

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**

Documents Posted:

- 12/12/08: CIRB Acknowledgement of Leucovorin Shortage Memo
- 11/25/08: COG Temporary Shortage of Leucovorin Letter

Amendment Review (AR): **Review of AALL0631 Family/Patient Letter regarding Temporary Study Enrollment Suspension (Protocol Version Date 11/02/07)**

Documents Posted:

- 12/22/08: CIRB Approval of AALL0631 Family/Patient Study Suspension letter (Protocol Version Date 11/02/07)
- 11/24/08: COG Dear Parents Letter



COG-AALL06N1

Amendment Review (AR): Amendment #1B - Study Reactivation Memo (Protocol Version Date 12/04/06)

Documents Posted:

- 11/25/08: CIRB Acknowledgement of COG AALL06N1 Reactivation

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

COG-ACNS0333

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**

Documents Posted:

- 12/12/08: CIRB Acknowledgement of Leucovorin Shortage Memo
- 11/25/08: COG Temporary Shortage of Leucovorin Letter

COG-ACNS0334

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**

Documents Posted:

- 12/12/08: CIRB Acknowledgement of Leucovorin Shortage Memo
- 11/25/08: COG Temporary Shortage of Leucovorin Letter

COG-AEWS07B1

Continuing Review (CR): Continuing Review December 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 12/27/07)
- 12/22/08: CIRB Continuing Review Approval Letter (Protocol Version Date 12/27/07)
- 11/11/08: CIRB Continuing Review Reminder Notice
- Protocol Version Date 12/27/07
- Protocol Version Date 12/27/07 - Highlighted Changes
- Informed Consent Document for Protocol Version Date 12/27/07 - Initial Diagnosis
- Informed Consent Document for Protocol Version Date 12/27/07 – Recurrence
- 10/07/08: DSMC Report
- 08/25/08: Study Progress Report

COG-ANBL0421

****Closed to Accrual by COG - Effective December 19, 2008****

Amendment Review (AR): **Acknowledgement of ANBL0421 Study Closure (12/19/08)**

Documents Posted:



- 12/23/08: CIRB Acknowledgement of COG ANBL0421 Study Closure
- 12/19/08: COG Closure of ANBL0421

COG-AOST0331

Amendment Review (AR): **Physician Notice - Shortage of Leucovorin**
Documents Posted:

- 12/12/08: CIRB Acknowledgement of Leucovorin Shortage Memo
- 11/25/08: COG Temporary Shortage of Leucovorin Letter

COG-ARET0331

****Closed to Accrual by COG - Effective December 19, 2008****

Amendment Review (AR): **Acknowledgement of ARET0331 Study Closure (12/19/08)**

Documents Posted:

- 12/29/08: CIRB Acknowledgement of Suspension of Enrollment and Treatment on ARET0331
- 12/19/08: Suspension of Enrollment and Treatment on ARET0331

ECOG-E1302

Amendment Review (AR): **Closure to Accrual-Effective November 13, 2008**

Documents Posted:

- 12/15/08: CIRB Approval of Recruitment Materials (Protocol Version Date 11/17/08)
- 11/17/08: Physician Notification Letter
- 11/17/08: Participant Notification Letter
- 11/17/08: Health & Human Services Unblinding Memo
- 12/05/08: Primary Reviewer 1 Comments

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

ECOG-E1900

Amendment Review (AR): **Closure to Accrual-Effective November 17, 2008**

Documents Posted:

- 12/05/08: CIRB Approval of Recruitment Materials
- 11/17/08: ECOG Closure Notice
- 11/17/08: Physician Notice Letter

ECOG-E2499

Continuing Review (CR): Approval October 2008

Documents Posted:

- 10/20/08: Minutes – Continuing Review



Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

ECOG-E2603

Amendment Review (AR): Update #5 Approval 08/19/08

Documents Posted:

- 07/09/08: Change Memo (Protocol Version Date 07/09/08)
- 08/19/08: CIRB Update 5 Approval Letter (Protocol Version Date 07/09/08)
- Protocol Version Date 07/09/08

ECOG-E5202

Amendment Review (AR): **Protocol Notice: Shortage of Leucovorin**

Documents Posted:

- 12/22/08: CIRB Approval of Shortage of Leucovorin Protocol Notice

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

ECOG-E5202

Continuing Review (CR): Approval November 2008

Documents Posted:

- 11/07/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

ECOG-E5204

Amendment Review (AR) Update #3 Approval 12/07/08

Documents Posted:

- 11/26/08: Change Memo
- CIRB Application (Protocol Version Date 11/26/08)
- Summary of CIRB Application Revisions (Protocol Version Date 11/26/08)
- 12/08/08: CIRB Update 3 Approval Letter (Protocol Version Date 11/26/08)
- Protocol Version Date 11/26/08
- Informed Consent Document for Protocol Version Date 11/26/08 [Up3]

ECOG-E5204

Amendment Review (AR): **Protocol Notice: Shortage of Leucovorin**

Documents Posted:

- 12/24/08: CIRB Approval of Shortage of Leucovorin Memo

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.



NCCTG-N0574

Continuing Review (CR): Approval October 2008

Documents Posted:

- 10/20/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

NCIC CTG-PR.11

Amendment Review (AR) Patient Recruitment Video Approval 08/14/08

Documents Posted:

- 12/15/08: CIRB Acknowledgement of Receipt-Patient Recruitment Video
- 11/18/08: NCIC Response to CIRB
- 08/15/08: CIRB Approval of Recruitment Materials (Protocol Version Date 08/06/08)
- 08/06/08: NCIC Response to CIRB

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

NSABP-B-33

Continuing Review (CR) Approval November 2008

Documents Posted:

- 11/07/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

NSABP-B-43

Continuing Review (CR) Approval December 2008

Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 05/28/08)
- 12/29/08: CIRB Continuing Review Approval Letter (Protocol Version Date 05/28/08)
- 12/19/08: NSABP Cover Letter
- 11/11/08: Continuing Review Reminder Notice
- Protocol Version Date 05/28/08
- Informed Consent Document for Protocol Version Date 05/28/08 [CR Dec08]
- Informed Consent Document-Instructions for Local IRBs (Protocol Version Date 05/28/08)
- Informed Consent Document (Pre-Entry) for Protocol Version Date 05/28/08 [CR Dec08]
- Informed Consent Document (Pre Entry)-Instructions for Local IRBs (Protocol Version Date 05/28/08)



NSABP-B-39/RTOG-0413

Continuing Review (CR) Approval November 2008

Documents Posted:

- 11/07/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

NSABP-R-04

Continuing Review (CR) Approval November 2008

Documents Posted:

- 11/07/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

RTOG-0436

Amendment Review (AR) Update #1 Approval 12/18/08

Documents Posted:

- 08/12/08: Change Memo (Protocol Version Date 08/12/08)
- 04/24/08: Change Memo (Protocol Version Date 08/12/08)
- CIRB Application (Protocol Version Date 08/12/08)
- Summary of CIRB Application Revisions (Protocol Version Date 08/12/08)
- 12/18/08: CIRB Update 1 Approval Letter (Protocol Version Date 08/12/08)
- Protocol Version Date 08/12/08
- Informed Consent Document for Protocol Version Date 08/12/08 [Up1]

RTOG-0521

Continuing Review (CR): Approval October 2008

Documents Posted:

- 10/20/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

RTOG-0522

Continuing Review (CR): Approval October 2008

Documents Posted:

- 10/20/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

SWOG-S0226



Continuing Review (CR): Approval October 2008
Documents Posted:

- 10/20/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

SWOG-S0124

Continuing Review (CR): Approval December 2008
Documents Posted:

- CIRB Continuing Review Application (Protocol Version Date 06/29/07)
- 12/30/08: CIRB Continuing Review Approval Letter (Protocol Version Date 06/29/07)
- 11/07/08: Continuing Review Reminder Notice
- Protocol Version Date 06/29/07
- 10/30/08-11/02/08: Study Summary
- 05/09/08: DSMC 05/02/08 Meeting Minutes

SWOG-S0500

Continuing Review (CR): Approval October 2008
Documents Posted:

- 10/20/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

SWOG-S0518

Continuing Review (CR) Approval November 2008
Documents Posted:

- 11/07/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

SWOG-S0777

Amendment Review (AR): **Participation in MRI Correlative is NOT Mandatory for Institutions**

Documents Posted:

- 12/17/08: CIRB Acknowledgement of MRI Memo
- 12/12/08: SWOG MRI Memo



SWOG-S0777

Continuing Review (CR) Approval November 2008
Documents Posted:

- 11/07/08: Minutes – Continuing Review

Additional documents associated with this action have been previously posted the Study Activity Update and are available on the website.

Serious Adverse Events

**Study: CALGB SWOG-C80405
SAE Posted: 1653936 FU1**

**Study: ECOG E1105
SAE Posted: 1653936 FU1**

**Study: ECOG E1305
SAE Posted: 1653936 FU1**

**Study: ECOG E1505
SAE Posted: 1653936 FU1**

**Study: ECOG E2100
SAE Posted: 1653936 FU1**

**Study: ECOG E4599
SAE Posted: 1653936 FU1**

**Study: ECOG E4A03
SAE Posted: 1940429 FU1**

**Study: ECOG E5103
SAE Posted: 1653936 FU1**

**Study: ECOG E5202
SAE Posted: 1653936 FU1**

**Study: ECOG E5204
SAE Posted: 1653936 FU1**

**Study: NSABP B-34
SAE Posted: 200811207 Safety Update 92 FU1, 200815097 Safety Update 79 FU1**

Study: NSABP B-38



SAE Posted: AR200805002972 FU1, DE200703003014 FU1, DE200805000250 FU1, MX200709003417 FU1

Study: NSABP B-40

SAE Posted: 1653936 FU1, 231325 FU4, 257362 FU1, 261116 FU3, AR200805002972, DE200703003014 FU1, MX200709003417 FU1

Study: NSABP C-08

SAE Posted: 1653936 FU1, 1653936 FU2, 231325 FU4, 257362 FU1, 261116 FU3

Study: SWOG S0232

SAE Posted: 1940429 FU1

Study: SWOG S0502

SAE Posted: 1653936 FU1

Study: SWOG S0518

SAE Posted: 1653936 FU1

Study: SWOG S0600

SAE Posted: 1653936 FU1

Study: SWOG S0777

SAE Posted: 1940429 FU1

Corrections to Previous Study Activity Updates

GOG-0218

Amendment Review Revision #4 Approval 09/05/08

Documents Posted: Protocol Title

Correction:

Title of Protocol was corrected per Revision #4.

NSABP-R-04

Continuing Review (CR) Approval November 2008

Documents Posted:

Informed Consent Document (Main) for Protocol Version Date 09/04/08
[CRNov08]



Informed Consent Document (Add 1) for Protocol Version Date 09/04/08
[CRNov08]

Informed Consent Document (Add 2) for Protocol Version Date 09/04/08
[CRNov08]

Correction:

Per NSABP, Consent Form Addendum 1 & Consent Form Addendum 2 were posted separately from the main consent document. There were no changes to any consent form documents.

If you have any questions about your local review process, please contact your Local IRB office.

If you have any questions about the CIRB Initiative, please contact the CIRB at ncicirbcontact@emmes.com.